IN THE UNITED STATES AND TRADEMARK OFFICE BEFORE THE TRADE MARK AND APPEAL BOARD

SAWATACON LIMITED and Dr. THOMAS M. SAWA, Petitioners, V. BRACE INTERNATIONAL, INC Registrant.	)	#76291518 Cancellation No. 92047383

Response to Letter of Suspension

I am in receipt of the Notice of Suspension dated January 25, 2008. It is unfortunate the focus of the suspension is oriented around technicalities rather the actual substance of my application which is the illegal use of my surname to promote unendorsed products. This is virtually tantamount to a type of identity fraud that should not be tolerated in the area of intellectual property, patents and trade-marks because of its grossly misleading aspects.

My second response to the suspension is that my present application is significantly different from my previous application in that it is based on fraud – identity fraud to be exact. My surname is being used without my permission to promote products. This is grossly misleading and unfair in that it misleads the public as to the creating and endorsement of a product. In addition, it is an undisputed fact that I was the original historical inventor of the shoulder brace product in dispute. Please see attached articles confirming this as follows: Journal of Sport Rehabilitation, article dated 1996; and reference in text-book by W. E. Prentice on Athletic Training, eleventh edition page 716 numbers 17 and 47.

Dated this 11TH of February, 2008.

Thomas M Sawa

Thomas M. Sawa D.C.F.C.C.S.S. (c)

Thomas M Sawa

Sawatacon – Dr. Thomas M. Sawa

- President, C.E.O, Director of Sawatacon

ELEVENTH EDITION

ARNHEIM'S PRINCIPLES OF Athletic Training

A COMPETENCY-BASED APPROACH

William E. Prentice

A

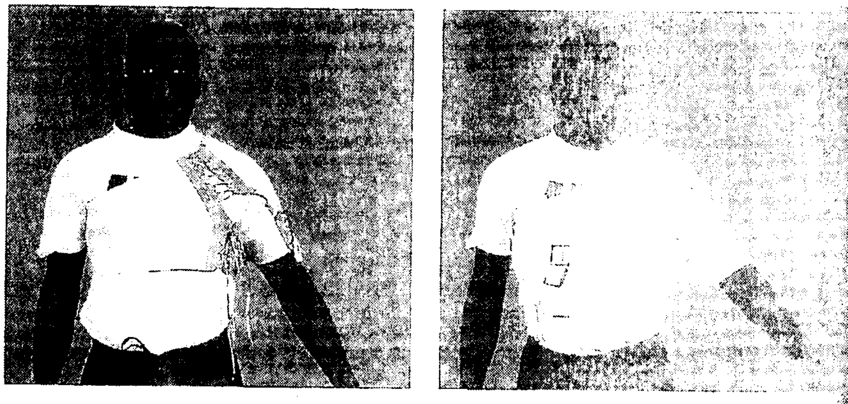

Figure 22-31

Protective braces for the shoulder.

Immobilization after Injury

Rehabilitation programs should be tailored to the individual athlete's ne[illegible] gressive approach should be used for throwers and swimmers. The length [illegible] mobilization period will vary depending on the structures [illegible], the sev[illegible] injury, and whether the injury is treated conservatively or surgically by the [illegible] Regardless of the injury, the injured athlete usually begins to exercise [illegible] while wearing an immobilization device (Figure 22-31). [illegible] be unnecessary to wear a sling or brace at all. Other [illegible] require [illegible] be worn twenty-four hours a day and removed only [illegible] tain injuries may require that a sling be worn only at night [illegible] ing, that a motion-limiting brace be worn during competition [illegible] that no sling or brace be worn after the first couple of weeks [illegible] an angle of 90 degrees be limited for a certain number of weeks. Progress[illegible] of motion and strengthening techniques should be dictated [illegible] the physiological process of healing and is generally determined by a lack [illegible] swelling associated with increased activity.[35]

General Body Conditioning

It is essential for the athlete to maintain a high level of [illegible] throughout the rehabilitation process. For shoulder joint [illegible] activi[illegible] running, speed walking, or riding an exercise bike may be used to m[illegible] diorespiratory endurance. Because many athletic activities [illegible] gaging in such training for a shoulder injury is more useful [illegible] ming for the rehabilitation of an ankle sprain. Athletes engaged in sports [illegible] upper-extremity endurance, such as swimming and throwing, should be [illegible] to these activities as soon as the activities can be tolerated. [illegible] activities may be modified such that the athlete can [illegible] flexibility, and neuromuscular control throughout the rest [illegible] riod of shoulder rehabilitation. Even though weight bearing [illegible] rehabilitation of the upper extremity, aquatic exercise [illegible] it can help with both maintaining cardiorespiratory [illegible] also [illegible] ing of the shoulder complex.[35]

Shoulder Joint Mobilization

Normal joint arthrokinematics must be maintained for the [illegible] full-range physiological movement. Mobilization techniques should be used [illegible] there is some limitation in motion that can be attributed to tightness [illegible] capsule or surrounding ligaments rather than to tightness of [illegible] units.[12] Mobilization techniques, including inferior, anterior [illegible]

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Journal of Sport Rehabilitation, 1996, 5, 143-150

Evaluation of Shoulder Instability Braces

Mark DeCarlo, Kathy Malone, Brad Gerig, and Mike Hunker

The comparative abilities of three types of shoulder orthoses to limit motion following isokinetic exercise were studied on 10 male subjects. Maximum active abduction, forward flexion, and external rotation were measured under a control and three braced conditions. Braced conditions included Sawa, Duke Wyre, and Shoulder Subluxation Inhibitor. Subjects performed 10 repetitions each of flexion/extension and abduction/adduction exercise at isokinetic speeds of 120 and 180°/s. Data were analyzed using a paired t-test and ANOVA. Significant differences were found for each of the devices in pre/post goniometric measurements of forward shoulder flexion. Only the Sawa brace demonstrated significant pre/post change for shoulder abduction. No significant differences were detected in any of the devices for external rotation. A trainer who is selecting a motion-limiting shoulder device for an athlete returning to competition following injury should consider the "loosening" effect that may occur during activity as well as the desire for overhead motion.

An athlete is most vulnerable to suffering an anterior dislocation when the arm is abducted and externally rotated. Forced horizontal extension or a posterior blow to the shoulder with the arm in this position can take the arm past its physiological limits and dislodge the humeral head from the glenoid fossa.

Shoulder stabilization in athletics has included a variety of taping and strapping techniques and, more recently, the introduction of several braces. Whether utilized prior to or following surgical intervention or in place of surgery, shoulder braces may allow athletes with anterior glenohumeral instability to participate in sport. Although a variety of devices are available on the market, practitioners generally choose from a few commonly used and well-known shoulder braces.

Shoulder braces are used to limit the motion of the glenohumeral joint, thereby preventing the arm from achieving a position that might lead to subluxation or dislocation should a direct or indirect outside force be applied. For the glenohumeral joint, the position at which the ligaments and capsule are potentially compromised is the position of maximum tightness (abduction and external rotation) known as the "close-packed position" (1). As with other protective devices, a shoulder brace that is prescribed for an injured athlete returning to competition must allow safe and effective participation without placing opposing players at risk, and game officials

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with athletes. Any device utilized by sports medicine professionals to return an athlete to competition should protect the injured area without allowing further injury. However, the device should not unnecessarily prevent the athlete from performing safe movements.

Each of the three braces studied limited motion in the sagittal and frontal plane. Due to its ability to maintain preset limitations in the frontal plane (limiting abduction) while at the same time allowing movement in the sagittal plane (permitting forward flexion), the SSI may be the most appropriate brace for the athlete desiring some degree of overhead arm motion. For example, the SSI brace may be more appropriate for returning a wide receiver to football activities than a brace which restricts overhead motion entirely. The SSI has the added benefit of a hard shell covering to protect against posterior blows received in football. A Sawa or Duke Wyre brace may be a more suitable choice for a football lineman or ice hockey player, for example, who is not as concerned with overhead arm motion.

Further studies should evaluate shoulder braces following actual sports participation rather than controlled isokinetic exercise, measure specific endpoints of motion in braces (including horizontal extension), use injured athletes as subjects, and test other braces currently in use.

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ARTICLES

DEPARTMENTS

An Alternate Conservative Management of Shoulder Dislocations and Subluxations

Thomas M. Sawa, BSc, DC, FCCSS(C)

ABSTRACT: This paper presents clinical observations/results of the application of an alternate method to traditional conservative management of subluxations and dislocations of the glenohumeral joint on major junior hockey players. The proposed program involves three stages: 1) rest and nutrition, 2) interferential current and faradic muscle stimulation, and 3) a traditional progressive-resistance weight-training program in conjunction with a specially designed orthosis. Current scientific theory on soft tissue healing and repair is reviewed as the backdrop to the proposed regimen. The resulting 100% success rate is compared to the success rate of conventional conservative therapeutic programs. The orthosis is a potentially useful therapeutic device permitting safe ranges of shoulder movement during the healing process, but scientific investigation is needed to determine the precise effect of the orthosis within the proposed therapy program.

Therapeutic management of dislocations and subluxations of the glenohumeral joint presents special problems for the athletic trainer. In 1975, Lipscomb (14) reported a recurrence rate of dislocation/subluxation of the glenohumeral joint of 83% to 90% in athletes under 20 years of age; a more recent study reported a recurrence rate of 90% to 95% in a similar population (5). It is estimated that athletic activity accounts for nearly 70% of all dislocations/subluxations to the shoulder complex (26).

From a therapist's perspective, a success rate of 5% to 17% (those that do not reoccur) is undesirable, and perhaps is indicative of shortcomings in traditional conservative therapeutic management and methodology. This paper will present an alternative conservative management of dislocations and subluxations in the glenohumeral joint.

The recurrence rate is actually accounted for by the anatomical structure of the shoulder itself. Not only is the relation of the size and orientation of the fossa problematic, but "[s]tability of the shoulder depends on the soft tissues . . . that surround the shoulder. Once soft tissue becomes lax, instability of the shoulder is an understandable sequela . . . (26)."

Jobes (12) felt that joint mobilization is integral to restoring normal range of motion and that "disuse itself has the effect of increasing the rate of metabolism of the unused structure." Further, "[l]igaments and tendons become thicker with stress [and] their intermolecular binding becomes stronger. The opposite effects occur with lack of stress. The rate at which this occurs seems to be related to the metabolic rate of the structure involved (4)." Unfortunately, both the conservative and surgical methods of treatment involve various measures of immobilization, and the period of immobilization is directly related to the period of rehabilitation.

Current research also has made available other data relevant to tissue rehabilitation. Well worth consideration in the clinical setting are: the therapeutic importance of deep circulation, how capillary beds empty without joint movement, and the importance of fibre recruitment and effusion reduction (6,18,19,23-25). The problem for athletic trainers is how to coordinate this information with the apparent paradox that both rest and mobilization are indicated modes of therapy.

Population Sampled

Eleven Major League amateur hockey players between 15 and 20 years of age comprised the study sample (see Table). For all participants (except participant #3), the therapy regimen was the same as that described below, the only variable being the duration of the treatment program, which was determined by the nature of the injury in each individual case.

The shortest duration of therapy was a period of 3 weeks, and the longest 7 weeks. At the time of initial evaluation, four subjects had had only one occurrence. The remaining seven had suffered more than one dislocation or subluxation.

Four athletes required surgical repair. All nine of the subjects who wore the orthosis had no recurrence, and only one of these patients did not receive any therapy. One subject (participant #3) received neither the therapy nor the brace. He was referred directly to an orthopaedic specialist, subsequently received surgical correction, and underwent traditional postoperative therapy. Another subject (participant #8) underwent only the therapy program and did not wear the orthosis, but continued to play hockey.

Method and Materials

The therapy program was divided into three phases: 1) rest and nutrition, 2) a strictly defined muscle stimulation program, and 3) a full weight-training regimen. The program was based on current knowledge of soft tissue repair and was employed in conjunction with a specially developed dynamic orthosis.

The orthotic device was used throughout all phases of therapy, because it permitted restricted shoulder movement, and therefore enabled us to introduce active therapy earlier, even in time periods close to the actual occurrence of the trauma. The attachments and straps are designed specifically to enable various adjustments (Fig 1) by which the athletic trainer/therapist is able to restrict shoulder movement from 0° abduction (total immobilization) to full range of motion, 180° abduction.

As injury restrictions decline, the adjustable bindings enable the therapist to redefine the limits of movement and eliminate the risk of premature movement

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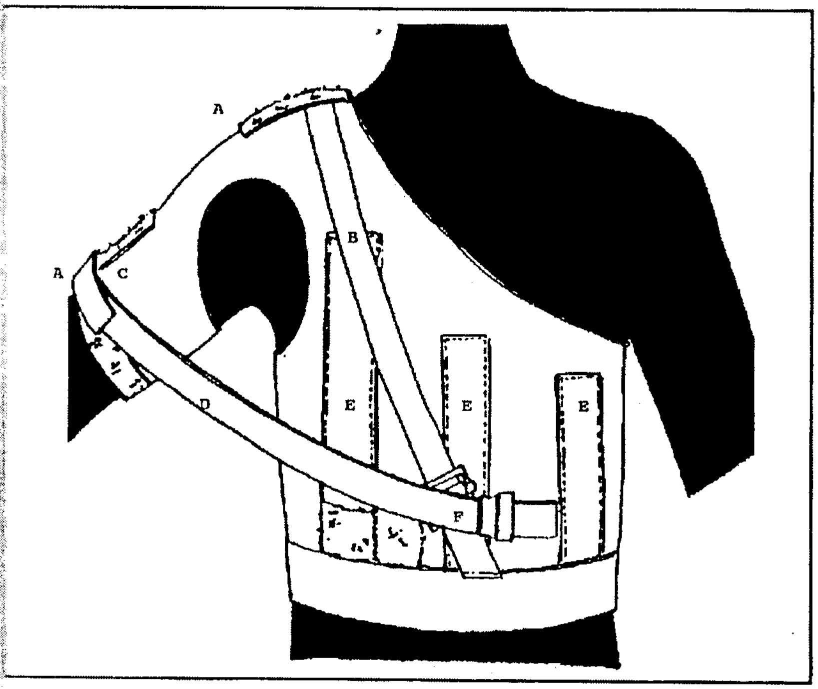

Fig 1.—Shoulder orthosis allows variable restriction of shoulder abduction. It is constructed of breathable, flexible materials to optimize fit and comfort. Labels on the illustration identify the following: A, Velcro Closures; B, Acromio-Clavicular Strap—used for A/C separations; C, Humeral Cuff; D, Glenohumeral Strap—for control abduction, adduction, flexion and extension; E, Extra Reinforcement—for fit and strength; and F, Buckle Closures.

the range of motion restricted by the nature of the trauma. This will serve to hasten movement to full external rotation and abduction while the shoulder is healing.

The orthotic device has essentially two functions: to stabilize and to restrict motion. Through its inherent elastic properties and the incorporation of contractile straps and bindings (Fig 1), the orthosis is able to mimic the natural holding elements of the glenohumeral joint. Additional strapping can be adjusted to restrict range(s) of motion in those areas requiring rehabilitation, allowing a normal range of motion in those areas that are not symptomatic.

Premodulated interferential current is used with levels beginning with a sedating stimulation mode (with a carrier frequency of 4080-4100 cps), gradually decreasing to motor stimulation (4000-4010 cps) (6,15). From a clinical perspective, the muscle tissue is being prepared for the more aggressive faradic stimulation to follow. By reducing inflammation and increasing circulation, interferential current therapy, in my opinion, enables the contractile elements to perform at their near-maximal levels (6,15). Similar findings were noted by Kotz in a December 1977 lecture on electrical stimulation of skeletal muscles at Concordia University.

It is with faradic stimulation that the musculotendinous complex of specific muscles can be isolated and strengthened (6,15). The precise effect of faradic stimulation is to increase strength in specific muscle groups in order to provide joint stability through the recruitment of motor neurons. Faradic stimulation maximizes the restoration of elastic properties of the holding elements by encouraging the correct parallel configurational arrangement of the collagen fibres within the cellular matrix (3).

In order to defray the onset of lactic acid accumulation (fatigue), it is necessary to provide proper ratios of rest-to-work for muscle activity (approximately a 3:1 work to rest ratio). This allows muscular contraction at or near maximum levels during repetition, without inducing (lactic acid) fatigue (9,22).

The six main factors to be considered in order to optimize the effects of electrical stimulation are: 1) the energy system used for muscle contraction, 2) the duration of current application, 3) the duration of rest between contractions, 4) the total number of applications and the length of time between them, 5) the type of current being used, and 6) current density (6,9,15,22).

Therapeutic Regimen

The subjects were informed of the necessity of proper nutrition, specifically because of the relation between work performance and the functional characteristics of water soluble vitamins (2,8,11). This facilitates work in therapeutic muscle stimulation by contributing to the energy production process within the cell.

The nature of the trauma sustained dictates the duration of rest and varies according to the type of therapy process to be implemented (ie, conservative versus postoperative). The rest period may vary from as little as a few days to as long as 6 weeks.

During the rest period, and in the absence of any neurovascular symptoms, it is beneficial to take advantage of neuromuscular integration—that is, the crossed extensor and lagged reciprocal extensor reflexes. Cuillo and Zarins (3) have suggested, and I would agree, that this will provide a training effect on the contralateral limb. In the program proposed here, therapeutic management is initiated by the application of interferential current.

The single most important clinical effect of interferential current stimulation is the role that it plays in muscle reeducation, specifically as the initiator of the recruitment of motor neurons. Interferential current stimulation is also effective in the areas of pain modulation and effusion control, promoting deep tissue circulation and minimizing fibrotic infiltration (4,7,13, 17,27). As the degree of comfort increases with an overall increase in joint mobility, the frequency of interferential current application decreases. A typical interferential current therapy schedule would alternate 1 day of stimulation with 1 day of rest continually for approximately 3 weeks. Interferential current stimulation would be completely phased out by approximately the fifth week of therapy.

Faradic stimulation should begin by approximately the tenth day following the introduction of interferential current therapy. Again, the procedure is repeated on alternate days for approximately 3 to 4 weeks. Faradic stimulation is, in essence, analogous to a progressive-resistance weight-training program. The muscle is prepared, at safe levels, to be able to endure a traditional weight-conditioning regimen. This begins with concentration on the external rotating musculature.

When full range of motion is restored, along with full joint play and flexibility with no pain being experienced, a progressive-resistance weight-training program is implemented. Therapy continues until the joint is completely rehabilitated. This includes approximate equal strength demonstrated by approximately a 10% difference as compared with the contralateral good limb, with equal flexibility, range of motion, and joint play. Clinical assessment of joint rehabilitation should take into consideration any anatomical and physiological restrictions as a result of surgical repair and demands that no pain be experienced.

Results

No participant in this study who wore the brace had a recurrence (see Table). The only athlete who did suffer recurrance, participant #8, underwent therapy but did not use the orthosis. Four of the participants eventually underwent corrective surgery; however, during the time period immediately preceding surgery, they wore the brace without incident. The following three case studies are presented here for illustrative purposes.

Case #2*

A 20-year-old hockey player dislocated his left shoulder while playing hockey. He reported several dislocations prior to medical assessment. While under care, he wore the orthosis, but did not undergo the other therapeutic measures. He continued to wear the orthosis during active play without recurrence until the shoulder was repaired surgically. He continues to use the orthosis during active play (see Table).

Case #6*

A 16-year-old athlete dislocated his right shoulder by falling on his outstretched upper limb while playing hockey. After a closed reduction, the shoulder was immobilized, and the subject was told to rest for 6 weeks.

The shoulder dislocated again upon returning to activity. At that time he had the following symptoms: positive apprehension sign, reduced internal/external rotation, atrophy of external rotators on posterior shoulder, normal neurovascular status with no axillary nerve or brachial plexus involvement, and normal radiograph (growth plates were open). He started therapy, as previously outlined, with the orthosis, and has returned to normal activity with no recurrence to date (see Table).

Case #7*

A 17-year-old hockey player suffered an anterior-inferior dislocation to his right glenohumeral joint. He was hit from behind and fell on his right elbow. He underwent a closed-reduction sling immobilization and was told to rest for 3 to 5 weeks. Upon returning to play, his shoulder was subsequently dislocated, and it reduced spontaneously. He underwent the aforementioned therapeutic program, including the use of the orthosis. To date, there has been no recurrence (see Table).

Discussion

Researchers are confirming that joint rehabilitation may be achieved through the strengthening of the musculotendinous complex, which supports and controls shoulder dynamics. The strengthening of contractile tissue elements is thought to be achieved by proper fibre recruitment and the induction of proper collagen synthesis and alignment.

Soft tissue repair occurs through a complex series of biomechanical, cellular and biochemical events. For example, it is at the molecular level that the dominant extracellular matrix components, collagen and proteoglycan, are altered in response to injury (1,8,16,21). The possibility that there is a relationship between the extracellular matrix and biomechanical demand should not be surprising.

Further, it would follow that soft tissue self-repair mechanisms, such as those involved in shoulder dislocations, are related to the biomechanical stresses simultaneously applied while healing processes occur. In order to obtain optimum healing therefore, it would be advantageous to utilize the available joint mechanics. If it is true that biomechanical demand can enhance soft-tissue repair, then this would then be the moulding factor responsible for the quality of soft tissue repair.

Traditional therapy programs call for immobilization and rest. This is counterproductive to the desired clinical end, which is to strengthen the injured tissue structures. As Ciullo and Zarins observed, "immobilization causes weakening of the musculotendinous unit.... [W]hen activity

* Refers to case in the Table.

Conservative Management

Case	Age**	Frequency	Therapy	Brace	Recurrence	Surgery	Follow-up
1	18	1	4 weeks	yes	no	no	3 years
2*	20	>1	no	yes	no	yes	3 years
3	18	1	no	no	—	yes	2 years
4	19	1	3 weeks	yes	no	no	2 years
5	19	>1	3 weeks	yes	no	no	3 years
6*	15	>1	6 weeks	yes	no	yes	3 years
7*	17	1	4 weeks	yes	no	no	4 years
8	19	>1	3 weeks	no	yes	no	3 years
9	18	>1	5 weeks	yes	no	yes	4 years
10	17	>1	4 weeks	yes	no	no	2 years
11	17	>1	4 weeks	yes	no	no	2 years

* Case studies reported in text
** Age at initial assessment

is resumed, the musculotendinous unit is at risk, lacking contractility, viscoelasticity, and strength. *Rehabilitation can be hastened by early motion* (emphasis added) (3)."

The therapeutic program outlined above is intended to eliminate complications concomitant with traditional immobilization. In contrast to the 5% to 17% success rate of traditional therapy (5, 14), this program is producing a success rate of 100%. Of the subjects who wore the orthosis, none have experienced recurrent dislocation to date (see Table).

This therapy program enables the athletic trainer to mimic nature and implement a natural healing process. Just as electrical stimulation enhances the *biochemical* and cellular changes necessary for soft tissue repair, so does the orthosis act to enhance the necessary *biomechanical* stresses.

The proposed program may be considered a practical application of the results of researchers who have suggested that the biomechanical process is the initiator of soft tissue healing (1). Movement has the therapeutic value of initiating the healing process.

Notwithstanding the preliminary and clinical nature of these results, it is clear that the therapeutic program correlates highly with injury nonrecurrence, and that the orthosis permits a safe, controlled movement of a subluxated/dislocated shoulder. It might be the biomechanical nature of the limited mobility that the orthosis allows that enables rehabilitation to proceed at a more natural pace and accounts for the encouraging results observed thus far.

Presently, these results are merely clinical observations obtained strictly from clinical settings. Yet, it appears that the orthosis has intrinsic value. What remains to be resolved is the relationship between each of the phases of the program outlined in this paper and the orthosis. Determining the precise role that this orthosis has in the healing process can only be established through thorough scientific research.

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